

## **REMARKS**

This preliminary amendment is filed concurrently with a Request for Continued Examination (RCE) and a Rule 132 declaration by inventor Marcus B. Gohlke.

Applicant does not believe that any fees are due at this time; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to this document, the Commissioner is authorized to deduct the fees from Howrey Simon Arnold & White, LLP Deposit Account No. 01-2508/13479.0002.CPUS01/BNT.

Applicant makes the following comments regarding the rejections of the claims made in the Final Office Action dated May 9, 2003.

### **I. Rejection under 35 U.S.C. § 112, second paragraph**

Claims 1, 3, and 5-18 were rejected under 35 U.S.C. § 112, second paragraph as being allegedly indefinite in claiming the subject matter of the invention. The Examiner was concerned regarding what times were encompassed by the phrase “an extended period of time”.

Applicant maintains that the inventive compositions can be safely administered for an extended period of time, with no specified endpoint. However, in order to expedite prosecution of the claims, independent claims 1 and 16-18 are amended in this preliminary amendment to indicate that the compositions can be safely administered daily for at least two weeks. As indicated in the specification and in the various declarations submitted during the prosecution of this patent application, the negative effects of either beta-glucan or lactoferrin alone can be observed or measured within two weeks (or as short as one or several hours). The inventive combined compositions can be safely administered for days, weeks, months, and so on. Applicant does not know of a specific “upper limit” for the duration of administration, and therefore does not indicate any such limitation in the claims.

Applicant respectfully requests that the rejections of claims 1, 3, and 5-18 under 35 U.S.C. § 112, second paragraph be withdrawn.

## **II. Rejection under 35 U.S.C. § 102**

Claims 1, 5, and 12-14 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,406,897 B1 (hereinafter “the ‘897 patent”).

As described in Applicant’s Response filed February 3, 2003, the ‘897 patent describes the chemical synthesis of covalently coupled glucan-protein conjugates. Lactoferrin is one of many proteins suggested as being suitable for this chemical modification.

The currently pending claims describe compositions containing lactoferrin and beta-glucan. The ‘897 patent does not describe such a composition, but rather describes a single coupled glucan-lactoferrin molecule that is covalently linked.

Applicant respectfully requests that the rejections of claims 1, 5, and 12-14 under 35 U.S.C. § 102 be withdrawn.

## **III. Rejection under 35 U.S.C. § 103**

Claims 1, 5-11, 16, and 17 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over the ‘897 patent described above.

Applicant maintains, as described in the previous section, that the suggestions of the ‘897 patent to chemically synthesize a covalently linked glucan-protein molecule does not in any manner render the claimed compositions comprising lactoferrin and beta-glucan obvious.

Claims 1, 3, and 5-18 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 5,296,464, U.S. Patent No. 5,783,569 , and U.S. Patent No. 5,670,138.

The Examiner indicated that “it is difficult to assess potential unexpected results because the periods of time [involved in the claims] are unclear.” The Examiner alleged that it was “not clear how long the individual ingredients can be administered before harmful side effects are seen and it is not clear how long applicant intend to administer the combined composition.”

Applicant has amended independent claims 1 and 16-18 to recite a specific period of time (two weeks, as described above regarding the rejection under 35 U.S.C. § 112, second paragraph). As described in the specification and in the various declarations submitted during the prosecution of this patent application, the negative effects of either beta-glucan or lactoferrin alone can be observed or measured within two weeks (or as short as one or several hours).

Applicant maintains that the claimed compositions show unexpected results in that they can be safely administered for an extended period of time (days, weeks, months), during which positive effects are observed without the undesirable negative side-effects encountered by administration of lactoferrin or beta-glucan alone.

Accordingly, Applicant requests that the rejections of claims 1, 3, and 5-18 under 35 U.S.C. § 103 be withdrawn.

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In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding objections and rejections are respectfully requested. All amendments are made in a good faith effort to advance the prosecution on the merits. Applicant respectfully submits that no amendments have been made to the pending claims for the purpose of overcoming any prior art

rejections that would restrict the literal scope of the claims or equivalents thereof. Applicant reserves the right to subsequently take up prosecution of the claims originally filed in this application in continuation, continuation-in-part, and/or divisional applications.

The Examiner is encouraged to call the undersigned should any further action be required for allowance.

Respectfully submitted,



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